Current Agreements

Dealdoc

Development and marketing agreement for RNA interference therapies for cardiovascular disease

Arrowhead Pharmaceuticals
Amgen

Sep 29 2016

Development and marketing agreement for RNA interference therapies for cardiovascular disease

Companies:	Arrowhead Pharmaceuticals Amgen
Announcement date:	Sep 29 2016
Amendment date:	Aug 02 2018
Deal value, US$m:	673.7 : sum of upfront, milestone and equity investments

Details

Announcement date:	Sep 29 2016
Amendment date:	Aug 02 2018
Industry sectors:	Bigpharma Pharmaceutical
Compound name:	AMG 890 (ARO-LPA)
Exclusivity:	Exclusive
Asset type:	Compound
Therapy areas:	Cardiovascular
Technology types:	RNA therapeutics
Deal components:	Development Marketing Option
Geographic focus:	Worldwide

Financials

Deal value, US$m:	673.7 : sum of upfront, milestone and equity investments
Upfront, US$m:	35 : upfront payments
Milestones, US$m:	10 : following administration of first dose of AMG 890 617 : additional milestone payments
Royalty rates, %:	n/d : based on sales
Equity, US$m:	21.7 : equity investment

Termsheet

December 2022

Arrowhead Pharmaceuticals announced a $25M milestone payment from Amgen.

This milestone was triggered by the first subject enrolled in Amgen’s Phase 3 trial of olpasiran.

Arrowhead is further eligible to receive up to an additional $535 million in aggregate development, regulatory, and sales milestone payments from Amgen and Royalty Pharma.

August 2018

Arrowhead Pharmaceuticals has earned a $10 million milestone payment from Amgen following the administration of the first dose of AMG 890, formerly referred to as ARO-LPA, in a clinical study.

Amgen is evaluating AMG 890 in a Phase 1 clinical study designed to assess its safety in volunteers with elevated levels of lipoprotein (a) (Lp(a)).

Emerging research has shown that elevated levels of Lp(a) are strongly associated with cardiovascular disease.

AMG 890 is an RNAi therapeutic designed to lower Lp(a) for the treatment of cardiovascular disease.

November 2016

Shares of Arrowhead Pharmaceuticals (ARWR) are up more than 18 percent to $8 per share in pre-market trading after Amgen bought a stake worth up to $675 million in the company to develop and commercialize RNA interference (RNAi) therapies for cardiovascular disease.

Under terms of the two deals, Pasadena, Calif.-based Arrowhead will receive $35 million in up-front payments and will then be eligible for up to $617 million in milestone payments.

The company will also get an additional $21.5 million from Amgen in the form of an Amgen equity investment.

Arrowhead will also be able to receive some royalties from sales.

Arrowhead is developing its RNAi ARC-LPA program.

The engineered molecules are designed to reduce elevated lipoprotein(a), which is a genetically validated, independent risk factor for atherosclerotic cardiovascular disease.

That is the first target for the Amgen and Arrowhead agreement.

Under the second agreement, Amgen will receive an option for a worldwide and exclusive license for a RNAi therapy for an undisclosed genetically validated cardiovascular target.

Under terms of both agreements, Amgen will be wholly responsible for clinical development and commercialization.

Press Release

December 2022

Arrowhead Pharmaceuticals Announces $25 Million Milestone Payment from Amgen

PASADENA, Calif.--(BUSINESS WIRE)-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced a $25M milestone payment from Amgen (NASDAQ: AMGN). This milestone was triggered by the first subject enrolled in Amgen’s Phase 3 trial of olpasiran. Arrowhead is further eligible to receive up to an additional $535 million in aggregate development, regulatory, and sales milestone payments from Amgen and Royalty Pharma plc (NASDAQ: RPRX).

“We are pleased with the great progress on the clinical development of olpasiran, which was developed using Arrowhead’s proprietary TRiMTM technology,” said Christopher Anzalone, Ph.D., Arrowhead’s president and CEO. “This is an important milestone for the program and for Arrowhead, as this is the second TRiMTM-enabled candidate to enter Phase 3 studies. Importantly, as our pipeline continues to advance expeditiously, we anticipate multiple Arrowhead therapies will also reach Phase 3 trials over the coming year.”

Olpasiran is a small interfering RNA (siRNA) originally developed by Arrowhead using its proprietary Targeted RNAi Molecule, or TRiM, platform and licensed to Amgen in 2016. It is designed to lower levels of lipoprotein(a) (Lp(a)), a genetically determined risk factor for cardiovascular disease. Phase 2 study results from the OCEAN(a)-DOSE study were presented at the American Heart Association Scientific Sessions 2022, where olpasiran demonstrated a significant and sustained reduction in Lp(a) levels over 36 weeks. These data were simultaneously published in the New England Journal of Medicine on November 6, 2022.

About Lp(a)

Lp(a) is genetically determined1-3 and a presumed independent risk factor for cardiovascular disease (CVD). Although an agreed upon threshold for elevated Lp(a) is not firmly established, approximately 20% of adults have Lp(a) >125 nmol/L (or approximately 50 mg/dL).1 Evidence has emerged from pathophysiological, epidemiologic, and genetic studies on the potential role of elevated Lp(a) in contributing to myocardial infarction, stroke, and peripheral arterial disease.3

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing.

August 2018

Arrowhead Pharmaceuticals Earns $10 Million Milestone Payment from Amgen

August 01, 2018 07:30 AM Eastern Daylight Time

PASADENA, Calif.--(BUSINESS WIRE)--Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced that it has earned a $10 million milestone payment from Amgen following the administration of the first dose of AMG 890, formerly referred to as ARO-LPA, in a clinical study. Amgen is evaluating AMG 890 in a Phase 1 clinical study designed to assess its safety in volunteers with elevated levels of lipoprotein (a) (Lp(a)). Emerging research has shown that elevated levels of Lp(a) are strongly associated with cardiovascular disease. AMG 890 is an RNAi therapeutic designed to lower Lp(a) for the treatment of cardiovascular disease.

Chris Anzalone, Ph.D., president and CEO at Arrowhead said, "We are thrilled that Amgen has advanced AMG 890 into a Phase 1 clinical study, resulting in a $10 million milestone payment to Arrowhead. Amgen has extensive expertise in developing and commercializing innovative cardiovascular medicines and we view our collaboration as further validation of the potential for Arrowhead's proprietary Targeted RNAi Molecule, or TRiM™, technology platform to generate compelling product candidates. Importantly, AMG 890 represents the third drug candidate enabled by TRiM™ to enter clinical development this year, following ARO-AAT and ARO-HBV."

"Amgen has a long-standing commitment to advancing innovative cardiovascular programs and the AMG 890 program is no exception," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We're excited to embark on the AMG 890 clinical program in which we hope to translate strong genetic insights and Arrowhead's exciting new RNAi technology into a treatment for patients with cardiovascular disease and elevated levels of Lp(a)."

Under the terms of the two cardiovascular agreements announced in September 2016, Arrowhead is eligible to receive up to $617 million in option payments, and development, regulatory, and sales milestone payments. Arrowhead is further eligible to receive up to low double-digit royalties for sales of products under the AMG 890 agreement and single-digit royalties for sales of products against an undisclosed target.

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November 2016

Arrowhead Pharma (ARWR) Announces Closing Of License And Collaboration Agreement With Amgen (AMGN)

PASADENA, Calif.--(BUSINESS WIRE)--Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) is pleased to announce that the license and collaboration agreement between Arrowhead and Amgen covering the novel RNAi ARC-LPA program has closed, following early termination of the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended.

About ARC-LPA

ARC-LPA is designed to reduce production of apolipoprotein A, a key component of lipoprotein(a), which has been genetically linked with increased risk of cardiovascular diseases, independent of cholesterol and LDL levels. ARC-LPA is Arrowhead's first drug candidate to use a subcutaneously administered delivery construct.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing. The company's pipeline includes ARC-520 and ARC-521 for chronic hepatitis B virus infection, ARC-AAT for liver disease associated with alpha-1 antitrypsin deficiency, ARC-F12 for hereditary angioedema and thromboembolic disorders, ARC-LPA for cardiovascular disease, and ARC-HIF2 for renal cell carcinoma.

September 2016

THOUSAND OAKS, Calif. – Shares of Arrowhead Pharmaceuticals (ARWR) are up more than 18 percent to $8 per share in pre-market trading after Amgen bought a stake worth up to $675 million in the company to develop and commercialize RNA interference (RNAi) therapies for cardiovascular disease.

Under terms of the two deals, Pasadena, Calif.-based Arrowhead will receive $35 million in up-front payments and will then be eligible for up to $617 million in milestone payments. The company will also get an additional $21.5 million from Amgen in the form of an Amgen equity investment. Arrowhead will also be able to receive some royalties from sales.

Arrowhead is developing its RNAi ARC-LPA program. The engineered molecules are designed to reduce elevated lipoprotein(a), which is a genetically validated, independent risk factor for atherosclerotic cardiovascular disease. That is the first target for the Amgen and Arrowhead agreement. Under the second agreement, Amgen will receive an option for a worldwide and exclusive license for a RNAi therapy for an undisclosed genetically validated cardiovascular target. Under terms of both agreements, Amgen will be wholly responsible for clinical development and commercialization.

RNA interference is a natural mechanism of gene silencing. Much of the interest in RNAi is based on the fact that the RNAi mechanism operates upstream of protein production by silencing the mRNA that codes for such proteins, thereby preventing the disease-causing proteins from being made in the first place.

ARC-LPA is designed to reduce production of apolipoprotein A, a key component of lipoprotein(a), which has been genetically linked with increased risk of cardiovascular diseases, independent of cholesterol and LDL levels. ARC-LPA is Arrowhead's first drug candidate to use a subcutaneously administered delivery construct.

Christopher Anzalone, president and chief executive officer at Arrowhead, said the company’s capabilities have become “increasingly validated” as more headway is made in the field of RNA-based therapies.

"We have made great advances to our proprietary subcutaneous RNAi delivery vehicle and in RNAi trigger modification and stabilization that enable rapid development of new RNAi therapeutics across multiple disease areas," Anzalone said in a statement.

Sean Harper, Amgen’s vice president of research and development, said the collaboration with Arrowhead allows Amgen to build upon its commitment to developing various therapeutic approaches to cardiovascular disease. Amgen already has a number of heart disease-related drugs in its pipeline, including its anti-cholesterol drug Repatha and heart failure drug Crolanor.

"Arrowhead's expertise in RNAi makes them a valuable partner as we translate genetic discoveries into potential therapies that can improve health outcomes for patients," Harper said in a statement.

Both companies anticipate the finalization of the deal by the end of the fourth quarter of 2016.

Several companies have focused their efforts on developing RNAi therapies. In addition to Arrowhead, leading RNAi companies include Boston-based Alnylam Pharmaceuticals (ALNY) and California-based Ionis Pharmaceuticals (IONS). Alnylam has two drugs in Phase III trials—patisiran and revusiran, for transthyretin amyloidosis. Ionis most recently completed a successful Phase III trial for nusinersen, a treatment for spinal muscular atrophy. Additionally Ionis has another RNA-targeting drug in late-stage development, volanesorsen for patients with either familial chylomicronemia syndrome or familial partial lipodystrophy.

Another company investing in RNAi therapies is Moderna Therapeutics, which has 11 drugs in its pipeline. In July, Moderna and Vertex (VRTX) inked a deal worth more than $315 million to develop treatments for cystic fibrosis using mRNA technology.

Filing Data

Not available.

Contract

Not available.